

Patent Office believes that all of the claims are anticipated by either *Schmidl* or *Henningfield*, then why does the Patent Office assert these same references in combination with other references in an obviousness rejection of the same claims? It is respectfully submitted that the Office Action in and of itself is inconsistent and does not comport with Patent Office procedures.

Regardless, the rejections of the claims, it is respectfully submitted, are not supported by the facts. Claims 1-2, 4, and 7-22 stand rejected as being anticipated by *Schmidl*. This rejection, it is respectfully submitted, is incorrect as a matter of law and fact. An anticipation rejection requires that "there must be no difference between the claimed invention and a reference's disclosure as viewed by a person of ordinary skill in the field of the invention." *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991). Accordingly, "for a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference." *In re Bond*, 910 F.2d 831 (Fed. Cir. 1990).

Schmidl fails to disclose or suggest a number of features of the claimed invention. *Schmidl* fails to disclose or suggest a caloric density of 1.4 kcal/mL. Each of the claims is limited to an enteral composition having a caloric density of 1.4 kcal/mL. As previously noted, this is a critical issue with respect to the patient population of Applicants' claimed invention. In contrast to the claimed invention, *Schmidl* states "the composition can also be in the form of a ready-to-use aqueous liquid which preferably has a caloric content of 1 kcal/mL." See column 7, lines 54-57.

If anything, *Schmidl* teaches away from the claimed invention. The Patent Office's statement that "inherently *Schmidl* discloses such a range [1.4 kcal/mL] because it claims similar components" is, it is respectfully submitted, ludicrous. The mere fact that a composition has

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lipids, carbohydrates, and protein does not mean the composition has the same caloric density as another composition including lipids, carbohydrates, and proteins. Inherency requires that the prior art reference and claimed composition must have the same physical attributes. Simply because a product has lipids, carbohydrates, and protein does not mean it has the same characteristics as another product having lipids, carbohydrates, and protein. There are millions of compositions including a lipid, a carbohydrate, and a protein that have different properties. Thus, clearly the anticipation rejection is improper in view of this fact alone.

Moreover, *Schmidl* fails to disclose the use of hydrolyzed proteins. Each of the claims requires that the protein source “consists essentially of” partially hydrolyzed proteins. *Schmidl* teaches that a number of proteins can be utilized. Accordingly, this is a further element of the claimed invention that is missing from *Schmidl* and a further reason why the anticipation rejection is not proper.

Moreover, with respect to Claims 4 and 12, these claims require that the composition includes 100% of the US RDA of vitamins and minerals in 1500 kcal. Even if *Schmidl* provides 100% of the US RDA of vitamins and minerals, which is not apparent from *Schmidl*, the product of *Schmidl* is designed to provide such in 1800-2000 calories. See column 7, lines 45-49. Accordingly, this element of dependent Claims 4 and 12 is not met by *Schmidl*.

It is clear from the above that *Schmidl* woefully fails to disclose, let alone suggest, the invention of Claims 1-2, 4, and 7-22. Therefore Applicants respectfully request that the anticipation rejection be withdrawn.

Claims 1-2, 4-5, and 7-22 stand rejected under 35 U.S.C. § 103 as being obvious in view of *Schmidl* and *Gray*. Applicants respectfully submit that this rejection, in and of itself, demonstrates that the Patent Office does not believe that the above discussed anticipation

rejection is proper. Why would the Patent Office propose that *Schmidl* in combination with another reference renders the claimed invention obvious if *Schmidl* alone anticipates the claimed invention? This inconsistency in the Office Action demonstrates, Applicants respectfully submit, that the rejections are not proper. Applicants also submit that this obviousness rejection is not proper.

As noted above, *Schmidl* fails to disclose a plethora of claimed elements. Once again: 1) *Schmidl* teaches away from the caloric density of the claimed invention; 2) *Schmidl* teaches that intact and hydrolyzed protein should be used interchangeably; and 3) *Schmidl* teaches a composition that can not be used with this patient population. If anything, *Schmidl* teaches away from the claimed invention.

Gray does not remedy the deficiencies of *Schmidl*. First, *Gray* teaches away from the claimed invention by using a high protein content of at least 22% of the calories of the product. Each of the claims of the present invention is limited to a protein source providing no more than 20% of the calories of the total composition.

Moreover, *Gray* teaches that the total non-protein calories per gram of nitrogen should be less than or equal to 70:1. The claims of the present invention require an NPC/gN of at least 90:1. Accordingly, even if *Schmidl* were combined with *Gray*, the claimed invention still would not be provided. Therefore, Applicants respectfully submit that the obviousness rejection is not proper and should be withdrawn.

Claims 1-2, 4-5, 7-16, and 21-22 stand rejected as allegedly being anticipated by *Henningfield*. Applicants respectfully submit that this rejection is clearly not proper; moreover, the Office Action in and of itself admits this anticipation rejection is not proper.

The Patent Office states on page 8 of the Office Action that “*Henningfield* does not teach the use of a partially hydrolyzed whey protein.” Applicants agree with this statement. Each of the pending claims is limited to the use of partially hydrolyzed whey protein. The Patent Office admits *Henningfield* does not disclose this element and accordingly the anticipation rejection is not proper. Once again, an anticipation rejection requires that the prior art discloses each and every claimed element. The Patent Office admits *Henningfield* does not disclose partially hydrolyzed whey protein, which is correct, and therefore this rejection is not proper and should be withdrawn.

Claims 1-2, 4-5, and 7-22 stand rejected under 35 U.S.C. § 103 as being obvious over *Schmidl*. Once again, Applicants question why the Patent Office is now asserting that *Schmidl* only renders the claims obvious when initially the Office Action stated that these claims were anticipated by *Schmidl*. Applicants respectfully request that the Patent Office take a consistent position. Does *Schmidl* anticipate the claims or not?

Regardless, Applicants respectfully submit that the claims are not obvious in view of *Schmidl*. In this regard, there are at least three claimed elements, noted above, missing from *Schmidl*. Nor are these missing elements suggested by *Schmidl*. For example, the fact that *Schmidl*’s composition can be easily diluted to achieve a caloric density of 1.4 is irrelevant. Where is the motivation to so dilute the composition? Unless the Patent Office can provide the motivation, the obviousness rejection is not proper and therefore should be withdrawn.

Claims 1-2, 4-5, and 7-22 stand rejected under 35 U.S.C. § 103 as being obvious in view of *Henningfield* in view of *Schmidl*. This rejection is at odds with the remaining portions of the Office Action. Each of *Henningfield* and *Schmidl* according to the Patent Office allegedly anticipate the claims. Then the Patent Office asserts that *Schmidl* alone renders obvious the

claimed invention. Now the Patent Office tacitly asserts that it is necessary to combine *Schmidl* and *Henningfield* to render obvious the claimed invention. Which is it?

Regardless, *Henningfield* and *Schmidl* still fail to disclose or suggest the claimed invention. Once again, *Henningfield* fails to disclose or suggest the use of partially hydrolyzed whey as a protein source. The Patent Office admits this. *Schmidl* fails to disclose the use of partially hydrolyzed whey as the protein source. Accordingly, where is the motivation in either of these two references to use partially hydrolyzed whey protein as the sole protein source? There is no motivation. Indeed, if anything, the references teach away from the claimed invention because they teach the exact opposite. This is indicative of non-obviousness, not obviousness. Accordingly, Applicants respectfully request the rejection be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of their patent application and earnestly solicit an early allowance of same.

Respectfully submitted,



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